



新昌县九信药业有限公司

Xinchang JiuXin Pharmaceutical Co.,Ltd

质量检测报告书

Certificate of analysis

报告书编号 certificate no. 20150506

检品名称 product	磺胺嘧啶 sulfadiazine	批号 batch no.	150506
数量 quantity	1000kg	报告日期 reporting date	07/05/2015(d/m/y)
生产日期 MFG DATE	06/05/2015(d/m/y)	失效日期 Expiry date	05/05/2019(d/m/y)
执行标准 according to	英国药典 2009 版 BP2009		

Tests	acceptance criteria	results
Characters	White, yellowish-white or pinkish-white, crystalline powder or crystals, it melts at about 255°C, with decomposition	Conforms
identification	1.The infrared absorption spectrum concordant with the spectrum of sulfadiazine CRS 2.The principal spot in TLC chromatogram obtained in position and size corresponds with sulfadiazine CRS	Conforms
heavy metals	≤20ppm	<20ppm
acidity	≤0.20ml	<0.1ml
Color of solution	≤Y <sub>5</sub> BY <sub>5</sub> or GY <sub>5</sub>	<Y <sub>5</sub>
Related substances	≤0.5%	<0.5%
loss on drying	≤0.5%	<0.18%
sulphated ash	≤0.1%	0.06%
Assay	99.0% ~101.0% (on the dried basis)	99.32%

结论：本品按英国药典 2009 版一部标准检验，结果符合标准

**Conclusion:** conforms with BP2009

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan